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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,921	09/24/2003	Paz Einat	68139-A/JPW/GJG/DNS	8511

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EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/671,921

Applicant(s)

EINAT ET AL.

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 6-8, 11, drawn to methods of treatment comprising administering inhibitors of human MKLP1, wherein the inhibitor is an antibody, classified in class 514, subclass 1.
- II. Claims 1, 2, 4, 6, 7, 9, and 11, drawn to methods of treatment comprising administering inhibitors of human MKLP1, wherein the inhibitor is an antisense oligonucleotide comprising SEQ ID NO: 3, classified in class 514, subclass 44.
- III. Claims 1, 2, 5-7, 10, and 11, drawn to methods of treatment comprising administering inhibitors of human MKLP1, wherein the inhibitor is an siRNA oligonucleotide comprising the sequence of SEQ ID NO: 4, classified in class 514, subclass 44.
- IV. Claims 12 and 14, drawn to an antisense oligonucleotide comprising SEQ ID NO: 3 and vectors thereof, classified in class 536, subclass 24.5.
- V. Claims 13 and 14, drawn to an siRNA oligonucleotide comprising the sequence of SEQ ID NO: 4 and vectors thereof, classified in class 536, subclass 24.5.
- VI. Claims 15 in 19, drawn to methods comprising comparing levels of MKLP1 polypeptide between healthy subjects and those having an apoptosis related disease, wherein low levels of MKLP1 polypeptide indicate the susceptibility to chemotherapeutic treatment, classified in class 435, subclass 4.

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- VII. Claims 16 and 20, drawn to methods comprising comparing levels of MKLP1 polypeptide between healthy subjects and those having an apoptosis related disease, wherein low levels of MKLP1 polypeptide indicate the susceptibility to chemotherapeutic treatment, classified in class 435, subclass 6.
- VIII. Claim 17, drawn to methods comprising determining the level of MKLP1 polypeptide before treatment and after treatment to determine the efficacy of chemotherapeutic treatment on the subject, classified in class 435, subclass 4.
- IX. Claim 18, drawn to methods comprising determining the level of MKLP1 mRNA before treatment and after treatment to determine the efficacy of chemotherapeutic treatment on the subject, classified in class 435, subclass 6.
- X. Claims 21-25, drawn to methods of obtaining a compound which inhibit MKLP1 polypeptide in cells, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV and V are related as product and process of use to those of II and III respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antisense and siRNA oligos of groups IV and V can be used in methods of inhibiting MKLP1 in vitro. Furthermore, since the keyword searches return different bodies of art, the searches are therefore divergent and non-coextensive, and it is a burden to search for such multiple inventions in a single application. Restriction is proper therefore.

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With the exception of those relationships defined above, the inventions of Groups I-X are directed to related processes or products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each group is considered mutually exclusive of any other group (again, excluding those relationships defined in the previous paragraph) and is not considered an obvious variant of one another, since each group utilizes a different inhibitor type or utilizes a different starting compound such as mRNA or a polypeptide, or has unique steps which are not shared by any other group as defined in the Group listings provided above. Furthermore, since the keyword searches return different bodies of art, the searches are therefore divergent and non-coextensive, and it is a burden to search for such multiple inventions in a single application. Restriction is proper therefore.

Claim 1 link(s) inventions I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. D. Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDS

JAMES SCHULTZ, PH.D.  
PRIMARY EXAMINER

